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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/582,971 07/07/00 PENNINGTON

S 60319-010

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HM22/0925

EXAMINER

PRASTHOFFER, T

ART UNIT

PAPER NUMBER

1627

DATE MAILED:

09/25/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

**Office Action Summary**  
*file copy*

Application No.

09/582,971

Applicant(s)

PENNINGTON, STEPHEN ROY

Examiner

Thomas W Prasthofer

Art Unit

1627

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 29 June 2001.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-30 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All   b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_                      6) ☐ Other:

### **Detailed Action**

#### **Change of Examiner**

The examiner of this application has changed from Barba Koroma to Thomas Prasthofer.

#### **Status of the Application**

Receipt is acknowledged of a response to a restriction requirement on June 29, 2001 in Paper No. 7.

#### **Status of the Claims**

Claims 1-30 are pending in the present application and are subject to restriction/lack of unity and election of species requirements.

#### **Restriction/Lack of Unity**

1. The present application is a 371 of PCT/GB99/00071 filed 01/08/1999. The previous restriction requirement mailed 03/27/2001 (Paper No. 4) was not made using lack of unity rules. The office action summary in Paper No. 4 states that 18 claims are pending in the application, not 30 claims as reflected in the office action. An adequate search of the prior art requires an election of species that was not included in the previous office action. For these reasons, a new restriction/lack of unity requirement and election of species requirement is set forth in this office action. The examiner regrets the need for a second requirement and the inconvenience that it may cause applicant. The examiner will strive to provide a compact prosecution of the present application.

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

**Group I**, claim(s) 1-5, 7-13, 15-29 (all in part), drawn to a method of selecting and/or identifying one or more protein affinity ligands that bind to one or more proteins of interest wherein the **affinity ligands are antibodies** and the method involves obtaining a **peptide mass fingerprint**.

**Group II**, claim(s) 1, 2, 4, 5, 11, 14-18, 28, 29 (all in part), drawn to a method of selecting and/or identifying one or more protein affinity ligands that bind to one or more proteins of interest wherein the **affinity ligands are NOT antibodies** and the method involves obtaining a peptide mass fingerprint.

**Group III**, claim(s) 1-11, 15, 16, 18-30 (all in part), drawn to a method of selecting and/or identifying one or more protein affinity ligands that bind to one or more proteins of interest wherein the **affinity ligands are antibodies** and the method involves obtaining a mass spectrometry based characterization **that is NOT a peptide mass fingerprint**.

**Group IV**, claim(s) 1, 2, 4-6, 11, 15, 16, 18, 28-30 (all in part), drawn to a method of selecting and/or identifying one or more protein affinity ligands that bind to one or more proteins of interest wherein the **affinity ligands are NOT antibodies** and the method involves obtaining a mass spectrometry based characterization other than a peptide mass fingerprint.

**Group V**, claim(s) 1-5, 7-11, 15, 16, 19-29 (all in part), drawn to a method of selecting and/or identifying one or more protein affinity ligands that bind to one or more proteins of interest wherein the **affinity ligands are antibodies** and the method involves obtaining a **protein characterization that is NOT mass spectrometry based**.

**Group VI**, claim(s) 1, 2, 4, 5, 11, 15, 16, 28, 29 (all in part), drawn to a method of selecting and/or identifying one or more protein affinity ligands that bind to one or more proteins of interest wherein the **affinity ligands are NOT antibodies** and the method involves obtaining a **protein characterization that is NOT mass spectrometry based**.

3. The inventions listed as Groups I-VI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special

technical features for the following reasons: The alternative language of claim 1 encompasses a method of selecting an affinity ligand that may or may not include mass spectrometry. The claim reads on any method of selecting or identifying one or more protein affinity ligands using any type of protein characterization. There is no special technical feature present in the claim.

4. Because these inventions are distinct for the reasons given above and
  - a. have acquired a separate status in the art as shown by their different classification (for example antibodies and non-protein ligands with affinity for a protein are classified differently as are methods that involve mass spectrometry as opposed to those that do not involve mass spectrometry;
  - b. have different and separately burdensome: manual and/or computer: structure, name and bibliographical searches; and
  - c. have divergent subject matter, restriction for examination purposes as indicated is proper.
5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).
6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 CFR 1.48(b) and by the fee required under CFR 1.17(h).

#### **Election of Species**

7. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

If applicant elects the invention of Group II, applicant is required to elect:

A. a species of non-antibody protein affinity ligand (e.g. protein, nucleic acid, small organic molecule, saccharide, lipid, inorganic molecule).

If applicant elects the invention of Group III, applicant is required to elect:

A. a species of mass spectrometry based protein characterization.

If applicant elects the invention of Group IV, applicant is required to elect:

A. a species of non-antibody protein affinity ligand (e.g. protein, nucleic acid, small organic molecule, saccharide, lipid, inorganic molecule) and

B. a species of mass spectrometry based protein characterization.

If applicant elects the invention of Group V, applicant is required to elect:

A. a species of "other" (non-mass spectrometry based) protein characterization.

If applicant elects the invention of Group VI, applicant is required to elect:

A. a species of non-antibody protein affinity ligand (e.g. protein, nucleic acid, small organic molecule, saccharide, lipid, inorganic molecule) and

B. a species of "other" (non-mass spectrometry based) protein characterization (e.g. sequence, molecular weight by SDS-PAGE, 2-D gel electrophoresis, binding affinity, enzymatic activity)

8. The species are distinct, each from the other, because they have different chemical structures with different chemical, physical, biochemical, and/or pharmacological properties or because they are different methods that require the use of different apparatus, reagents, and/or experimental conditions, and produce different results. Therefore, different issues of enablement and patentability apply to each species and each species represents patentably distinct subject matter.

9. Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

10. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Thomas Prasthofer** at telephone number **(703) 308-4548**. The examiner can normally be reached on Monday, Tuesday, Friday, and Saturday 8:00-6:30.

12. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jyothsna Venkat can be reached on (703) 308-2439. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-2742.

13. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist at (703) 308-1235.

Thomas Prasthofer, Ph.D.

September 18, 2001

DR. JYOTHSNA VENKAT PH.D.  
SUPERVISOR



DR. JYOTHSNA VENKAT PH.D.  
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